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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,914	05/30/2006	Christian Mauran	SOLO-1US	8708

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EXAMINER
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YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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11/10/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/580,914	<b>Applicant(s)</b> MAURAN ET AL.	
	<b>Examiner</b> DIANE YABUT	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2010 and 02 August 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 19-38 is/are pending in the application.
- 4a) Of the above claim(s) 19-24 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This action is in response to applicant's amendment received on 08/23/2010 and remarks received on 08/02/2010. The examiner acknowledges the amendments made to the claims. Claims 19-38 are pending in this application. Claims 19-24 and 38 are withdrawn from consideration.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 25-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. In claim 25 there is an inconsistency in the language of the preamble and that of body of the claim thus making their scope unclear. The preamble recites a device for packaging and conserving a flexible hydrophilic intraocular lens with the flexible hydrophilic intraocular lens only functionally recited, e.g. for packaging and conserving, thus indicating that the claims are directed to the subcombination, device. However lines 8-15 positively recite the flexible hydrophilic intraocular lens, as an element of the invention, e.g. placed on the injection support, thus indicating that the claims are directed to the combination of the device and the flexible hydrophilic intraocular lens. As such it is unclear whether applicant intends the claims to be drawn to the combination or the subcombination. Applicant is hereby required to indicate which, the combination

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(device and flexible hydrophilic intraocular lens) or subcombination (flexible hydrophilic intraocular lens) the claims are intended to be drawn and make the language consistent with this intent. For examination purposes, the claims will be considered as drawn to the combination, device and the flexible hydrophilic intraocular lens.

### ***Claim Objections***

4. Claims 26-37 are objected to because of the following informalities: The claims begin with "A device" and should rather read --The device--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 25, 27, 29, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mazzocco** (US 4,423,809) in view of **Eagles et al.** (US 5,616,148).

Regarding claim 25, Mazzocco discloses a device for packaging and conserving in a sterile condition a flexible hydrophilic intraocular lens (col. 4, ln. 33), comprising: an injection support (24); a flexible hydrophilic intraocular lens (23) placed on the injection support (24); a packaging enclosing at least the lens, the injection support and a volume of solution for conserving the lens which bathes the lens and keeps it hydrated, wherein:

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the injection support (24) is adapted receive and carry the lens flat; the lens is carried flat on the injection support (24) and immersed in a bath of liquid conserving solution contained in a rigid liquid-tight flask (21) which is closed, the assembly is in a sterilized condition (col. 4, ln. 44-63).

Mazzocco fails to disclose the injection support including an implantation end through which the lens can be slid and ejected for implantation, said injection support being adapted to be associated with an injection device including a thruster piston able to push the lens toward an implantation end of the injection support and the injection support adapted to carry out folding of the lens prior to the ejection of the lens via the implantation end.

Eagles et al. discloses an injection support (14) which is adapted to receive and carry the lens flat, the injection support including an implantation end (16) through which the lens can be slid and ejected for implantation, said injection support adapted to be associated with an injection device (12) including a thruster piston (18) able to push the lens toward the implantation end of the injection support (Fig. 11- 12), wherein the injection support is adapted to carry out folding of the lens prior to ejection of the latter via the implantation end (col. 4, ln. 43 - col. 5, ln. 2) to safely compress the lens for delivery through a small incision in the eye. It would have been obvious to one of ordinary skill in the art to substitute the injection support of Mazzocco with the injection support (and the associated injection device) of Eagles et al. in order to permit controlled compression of the deformable hydrophilic lens so that it may be inserted through a small incision in the eye.

Regarding claims 27, Mazzocco modified by Eagles et al. disclose the injection support is adapted to carry out folding by a simple translational movement imparted to the lens when the latter is pushed towards the implantation end (col. 4, ln. 43-64).

Regarding claim 29, Mazzocco modified by Eagles et al. disclose the injection support is carried removably by a stopper for closing the rigid flask (Mazzocco, col. 5, ln. 15-16).

Regarding claim 37, Mazzocco modified by Eagles et al. disclose the injection support (14) includes an adapter bush (22) forming a receptacle for the lens, the bush being adapted to be able to carry and receive different models of lens, and to be mounted in a cylindrical end portion of the injection support (14; Fig. 11).

7. Claims 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mazzocco** (US **4,423,809**) in view of **Eagles et al.** (US **5,616,148**) as applied to claim 25 above, and further in view of **Bazell et al.** (US **3,930,580**).

Regarding claim 26, Mazzocco modified by Eagles et al. disclose autoclaving the rigid flask containing the injection assembly and the lens (4, ln. 44-63), but fail to disclose the rigid flask is enclosed in an outer packaging envelope.

Bazell et al. disclose a steam sterilizable packaging envelope for maintaining medical and surgical instruments in sterile condition (see abstract). It would have been obvious to one of ordinary skill in the art to provide the device of Mazzocco modified by Eagles et al. in an outer packaging envelope in order to prevent contamination of the system prior to use.

Regarding claim 28, Mazzocco modified by Eagles et al. disclose the injection support is adapted to carry out folding by a simple translational movement imparted to the lens when the latter is pushed towards the implantation end (col. 4, ln. 43-64).

8. Claims 25, 27, and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Eagles et al.** (US **5,616,148**) in view of **Mazzocco** (US **4,423,809**) and **Feingold et al.** (US **5,728,102**).

Eagles et al. disclose a device for packaging and conserving in a sterile condition a flexible intraocular lens comprising: an injection support (14) which is adapted to receive and carry the lens flat (Fig. 12; col. 2, ln. 43-44), the injection support including an implantation end (16) through which the lens can be slid and ejected for implantation, said injection support adapted to be associated with an injection device (12) including a thruster piston (18) able to push the lens toward the implantation end of the injection support (Fig. 11-12), wherein the injection support is adapted to carry out folding of the lens prior to ejection of the latter via the implantation end (col. 4, ln. 43 - col. 5, ln. 2); a flexible lens (30) placed on the injection support (14; Fig. 11), the hollow cylindrical body (12) forms an axial end stop which prevents premature extraction of the thruster piston (18) from the hollow cylindrical body (Fig. 7).

Eagles et al. fail to disclose a hydrophilic lens and a rigid flask enclosing at least the lens, the injection support and a volume liquid solution which bathes the lens and keeps it hydrated. Mazzocco discloses a flexible hydrophilic intraocular lens (23) placed on the injection support (24); a packaging enclosing at least the lens, the injection

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support and a volume of solution for conserving the lens which bathes the lens and keeps it hydrated, wherein: the injection support (24) is adapted receive and carry the lens flat; the lens is carried flat on the injection support (24) and immersed in a bath of liquid conserving solution contained in a rigid liquid-tight flask (21) which is closed, the assembly is in a sterilized condition (col. 4, In. 44-63).

Mazzocco discloses the flexible hydrophilic lens has memory characteristics which enable the lens to be deformed during delivery and then return to its original configuration, full size and fixed focal length after insertion into the eye (col. 2, In. 3-17 and col. 7, In.27-32 of US Patent 4,573,998 which is incorporated by reference in col. 1, In. 7-12 and col. 4, In. 31-35). It would have been obvious to one of ordinary skill in the art to replace the lens in the device of Eagles et al. with the flexible hydrophilic lens of Mazzocco since the lens of Mazzocco provides the advantage of being able to return to its original shape, size, and focal length after deformation of the lens and insertion into the eye. Mazzocco discloses hydrating the lens during storage is advantageous because it eliminates the step of removing the lens from the packaging and converting the optical parameters of the lens in air to equivalent measurements when the lens is placed in the eye (col. 2, In. 3-34). In configuring the device of Eagles et al. to deliver a hydrophilic lens, it would have been obvious to one of ordinary skill in the art to maintain at least the lens and the injection support in the conserving solution inside a rigid flask as suggested by Mazzocco in order permit inspection of the optical parameters of the lens without removal of the lens from the injection support.



Eagles et al. modified by Mazzocco fail to disclose the injection support associated with an injection device, wherein the rigid flask and the cylindrical body of the injection device are adapted to be fixed to one another, the injection support extending into the liquid conserving fluid in the rigid flask.

Feingold et al. disclose preloading the lens and pre-assembling the injection system prior to packaging is advantageous because it reduces amount of packing and eliminates the step of loading the lens into the cartridge and injecting device which could potentially cause damage to the lens (col. 4, ln. 65 - col. 5, ln. 13). It would have been obvious to one of ordinary skill in the art to modify the device of Eagles et al. to pre-load and pre- assemble injection system (attach the injection support containing the lens to the injection device) in order to reduce amount of packaging and eliminate the risk of damaging lens during the step of loading the lens into the injecting device. Further, it would have been obvious to screw the mouth of the rigid flask to the distal end of the hollow body of the injection device, in place of the cap, during assembly of the device in order to seal the flask and maintain the solution inside the flask.

9. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Eagles et al.** (US 5,616,148) in view of **Mazzocco** (US 4,423,809) and **Feingold et al.** (US 5,728,102) as applied to claim 33 above, and further in view of **Figueroa et al.** (US 5,873,879).

Regarding claim 34, Eagles et al. modified by Mazzocco and Feingold et al. fail to disclose a seal adapted to be interposed between the axial end stop of the hollow

cylindrical body and a sealing block of the thruster piston when in its retracted end position of the hollow cylindrical body.

Figueroa et al. disclose a thruster piston having a seal (proximal seal 120) interposed between the axial end of a hollow cylindrical body and a sealing block (distal seal 120) of the thruster piston. Figueroa et al. discloses the seal and sealing block provide a level of resistance to provide more controlled operation of the plunger and prevent inadvertent movement of the thruster piston (col. 5, ln. 47-53). It would have been obvious to one of ordinary skill in the art to modify the thruster piston of Eagles et al. to include a seal and a sealing block to prevent inadvertent movement of the piston.

10. Claims 25, 27, 30, 31, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Figueroa et al.** (US **5,873,879**) in view of **Mazzocco** (US **4,423,809**).

Figueroa et al. disclose a device for packaging and conserving in a sterile condition a flexible intraocular lens comprising: an injection support (22) which is adapted to receive and carry the lens flat (Fig. 19; col. 4, ln. 22-35), the injection support including an implantation end (95) through which the lens can be slid and ejected for implantation, said injection support adapted to be associated with an injection device including a thruster piston (18) able to push the lens toward the implantation end of the injection support (Fig. 19-20), wherein the injection support is adapted to carry out folding of the lens prior to ejection of the latter via the implantation end (col. 4, ln. 60 - col. 5, ln. 25); a flexible lens (12) placed on the injection support (14; Fig. 11 ), the thruster piston (18) includes a non rotationally symmetrical operating stem

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(Fig. 2-4), wherein the hollow cylindrical body has an axial end provided with a non-rotationally symmetrical opening having a shape matching that of the operating stem (col. 3, In. 38-55), wherein the operating stem is so mounted as to be able to be rotated about its longitudinal axis between a locked position in which it cannot pass through the opening and an unlocked position in which it can pass through the opening.

Figuerola et al. fail to disclose a hydrophilic lens and a packaging enclosing at least the lens, the injection support and a volume liquid solution which bathes the lens and keeps it hydrated.

Mazzocco discloses a flexible hydrophilic intraocular lens (23) placed on the injection support (24); a packaging enclosing at least the lens, the injection support and a volume of solution for conserving the lens which bathes the lens and keeps it hydrated, wherein: the injection support (24) is adapted receive and carry the lens flat; the lens is carried flat on the injection support (24) and immersed in a bath of liquid conserving solution contained in a rigid liquid-tight flask (21) which is closed, the assembly is in a sterilized condition (col. 4, In. 44-63). Mazzocco discloses the flexible hydrophilic lens has memory characteristics which enable the lens to be deformed during delivery and then return to its original configuration, full size and fixed focal length after insertion into the eye (col. 2, In. 3-17 and col. 7, In.27-32 of US Patent 4,573,998 which is incorporated by reference in col. 1, In. 7-12 and col. 4, In. 31-35). It would have been obvious to one of ordinary skill in the art to replace the lens in the device of Figuerola et al. with the flexible hydrophilic lens of Mazzocco since the lens of Mazzocco provides the advantage of being able to return to its original shape, size, and

focal length after deformation of the lens and insertion into the eye.

Figueroa et al. discloses pre-assembling and preloading the injection device (i.e. the lens loaded in the injection support and the injection support attached with the injection device), but fail to disclose a rigid flask and the cylindrical body of the injection device are adapted to be fixed to one another, the injection support extending into the liquid conserving fluid in the rigid flask. Mazzocco discloses hydrating the lens during storage is advantageous because it eliminates the step of removing the lens from the packaging and converting the optical parameters of the lens in air to equivalent measurements when the lens is placed in the eye (col. 2, ln. 3-34). In configuring the device of Eagles et al. to deliver a hydrophilic lens, it would have been obvious to one of ordinary skill in the art to maintain at least the lens and the injection support in the conserving solution inside a rigid flask as suggested by Mazzocco in order permit inspection of the optical parameters of the lens without removal of the lens from the injection support. Further, it would have been obvious to screw the mouth of the rigid flask to the distal end of the hollow body of the injection device, in place of the cap, during assembly of the device in order to seal the flask and maintain the solution inside the flask.

### ***Response to Arguments***

11. Applicant's arguments filed 08/02/2010 have been fully considered but they are not persuasive.

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12. Applicant argues that Mazzocco does not teach an injection support 24 since it is meant to immobilize the intraocular lens and that the lens in Mazzocco is not bathed in liquid to keep it hydrated. However, the examiner asserts that the support or clamp fixture 24 is capable of being used to translate an intraocular lens and the liquid used in Mazzocco also aids to bathe the lens in addition to the purpose of duplicating optimal transmission characteristics of fluid in the eye. If the prior art structure is capable of performing the intended use, then it meets the claim.

13. Next, the applicant generally argues that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, since the injection support of Eagles et al. do not use a hydrophilic lens nor lens storage and Mazzocco stores a lens prior to implantation. However, Eagles et al. teach injecting or manipulating an intraocular lens with an injection support piston, which may be used within the device of Mazzocco for controlled manipulation of the lens in since Mazzocco teaches that the device may be used for "manipulation for placement of the intraocular lens structure within the eye" and not just for storage and inspection of the optical parameters of the lens (see abstract). It must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper.

14. Lastly, applicant generally argues the rationale by the examiner of why one skilled in the art would be motivated to use a hydrophilic lens of Mazzocco in Eagles et

al. or in Figueroa et al. with the benefit of space memory properties since both hydrophilic and hydrophobic share the same attributes of flexible lenses in general. The examiner asserts that the type of lens in Eagles et al. and Figueroa et al. is not specified, and therefore using the hydrophilic lens of Mazzocco has the benefits of memory characteristics, which may be functionally equivalent to a hydrophobic lens in this regard, but does not render the modification of using a hydrophilic lens unobvious.

### ***Conclusion***

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/  
Examiner, Art Unit 3734

/TODD E. MANAHAN/  
Supervisory Patent Examiner, Art Unit 3776